DENTSPLY

K083326

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510(k) SUMMARY
for
FluoroCore® 2

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

FEB 10 2009

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: November 3, 2008

2. Device Name:

- Proprietary Name: FluoroCore® 2
- Classification Name: Tooth Shade Resin Material; Dental Cement
- CFR Number: § 872.3690; § 872.3275
- Device Class: Class II; Class II
- Product Code: EBF; EMA

3. Predicate Devices:

Company	Device	510(k) No.	Date Cleared
DENTSPLY International	FluoroCore	K896564	9 February 1990
DENTSPLY International	Calibra	K040906	16 June 2004

4. Description of Device:

FluoroCore® 2 is a fluoride-releasing dual cure (chemical and/or light cure), radiopaque two-component core build-up material and post cement. The material is available in two shades and is delivered in double-barrel syringes.

5. Indications for Use:

Vital or non-vital tooth core build-up (replacement of existing restorations and/or tooth lost structure) as a base prior to fabricating an indirect restoration and as a post cement.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics

The FluoroCore® 2 is substantially equivalent to the predicate devices. The new device and predicate devices are similar in function, composition, and intended use.

Non-Clinical Performance Data

Toxicological Testing

Cytotoxicity and genotoxicity tests were performed in accordance with ISO 10993 and ISO 7405. FluoroCore® 2, including all colorants, has been demonstrated as biocompatible and safe for the same indication and type of tissue contact as the predicate devices.

Physical Properties

Testing was performed in accordance with ISO 4049 (*Dentistry – Polymer based filling, restorative and luting materials*). FluoroCore® 2 complies with ISO 4049.

Conclusion as to Substantial Equivalence

FluoroCore® 2 is substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Helen Lewis
Director of Corporate Compliance & Regulatory Affairs
DENTSPLY International, Incorporated
Susquehanna Commerce Center
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404

FEB 10 2009

Re: K083326
Trade/Device Name: FluoroCore® 2
Regulation Number: 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF, EMA
Dated: November 3, 2008
Received: November 12, 2008

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K083326

Device Name: FluoroCore 2

Indications for Use:

FluoroCore® 2 is indicated for vital or non-vital tooth core build-up (replacement of existing restorations and/or lost tooth structure) as a base prior to fabricating an indirect restoration and as a post cement.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083326